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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/537,971

06/09/2005

Yoshihiro Ohmiya

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WENDEROTH, LIND & PONACK, L.L.P.

1030 15th Street, N.W.,

Suite 400 East

Washington, DC 20005-1503

EXAMINER

NOAKES, SUZANNE MARIE

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

11/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/537,971	Applicant(s) OHMIYA ET AL.	
	Examiner SUZANNE M. NOAKES	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 17 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 17 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

1. The amendments and remarks filed 10 August 2009 are acknowledged.
Applicants have amended claim 16 and cancelled claims 23-25. Claims 16, 17 and 22 are pending and subject to Examination on the merits.

Withdrawal of Rejections/Objections

2. Any rejection/objection recited in the previous Office action and not explicitly restated below is hereby withdrawn.
3. The rejection of claims 16, 17 and 22-25 under 35 USC 112 1st paragraph – written description, New Matter, is withdrawn in view of the amendments to claim 16 which recites that the method utilizes SEQ ID NO: 2, which was originally disclosed in the original claims and specification.
4. The objection to the specification for introducing new matter is hereby withdrawn upon further consideration and upon Applicants Declaration and Remarks stating that all instances of the species *Cypridina noctiluca* was an error and should have recited *Vargula hilgendorfi*. It is noted that SEQ ID NO: 2 was originally filed in the claims and the specification; Applicants assert that the use of the wrong organism was merely a typographical mistake at the time of filing (see Declaration filed 02/27/2009, Remarks from the same date). It is noted that *V. hilgendorfi* is well known to contain this particular luciferase which is part of the monitor protein (a fusion protein of luciferase, cleavage site and yellow fluorescent protein) and thus one skilled in the art would be

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able to isolate and use the noted luciferase (which was first isolated in 1989) to make use the instant invention. On the other hand, a luciferase from *Cypridinia noctiluca* was not isolated until post-filing, albeit it was Applicants own work. However, all abbreviations in the specification referring to the *V. hilgendorfi* are to “Vluc” and not to “Cluc” thus also suggesting that the argument of a typographical error to be accurate. Thus, based on Applicants arguments and the assessment that SEQ ID NO: 2 was originally filed in the specification and the claims and thus fully disclosed and supported, changing the occurrences of *Cypridinia noctiluca* to *V. hilgendorfi* now fully supports the claimed invention, e.g. use of SEQ ID NO: 2. Thus, the objection to the specification is withdrawn.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 16, 17 and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-12 and 18 of U.S. Patent No. 7,544,484. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 9 of the '569 application is drawn to an isolated polynucleotide comprising SEQ ID NO: 1 which encodes a chimeric monitor protein of the following form: a *Vargula* luciferase and yellow fluorescent protein (YFP) which according to Figure 1b, also encodes for a linker peptide between the luciferase and YFP – said polynucleotide notably encodes for a protein which is 100% identical to the instant SEQ ID NO: 2 (see alignment below and results in SCORE). The other claims of the '569 application are drawn to vectors, transformants and methods of making said chimeric fusion proteins. As such, it would be obvious to use the noted DNA and

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encoded protein in the instant claimed methods for using such a chimeric fusion protein to quantitatively monitor the energy change in energy transfer between the YFP and luciferase.

RESULT 1

ADL56773

ID ADL56773 standard; DNA; 2502 BP.

XX

AC ADL56773;

XX

DT 03-JUN-2004 (first entry)

XX

DE DNA encoding chimeric protein #2.

XX

KW ds; gene; secretory chimeric protein; membrane-bound chimeric protein;

KW antidiabetic; antiinflammatory.

XX

OS Unidentified.

XX

FH Key Location/Qualifiers

FT CDS 1. .2502

FT /*tag= a

FT /product= "Chimeric peptide #2"

XX

PN WO2004022600-A1.

XX

PD 18-MAR-2004.

XX

PF 04-SEP-2003; 2003WO-JP011285.

XX

PR 06-SEP-2002; 2002JP-00261229.

PR 10-DEC-2002; 2002JP-00357407.

XX

PA (NAAD-) NAT INST ADVANCED IND SCI & TECHNOLOGY.

XX

PI Ohmiya Y, Ashitaka E, Ito S;

XX

DR WPI; 2004-248450/23.

DR P-PSDB; ADL56783.

XX

PT Chimeric secretory or membrane-bound protein containing an energy

PT generating protein and an energy accepting protein for use as a reporter

PT of gene expression.

XX

PS Disclosure; SEQ ID NO 2; 57pp; Japanese.

XX

CC The invention relates to secretory or membrane-bound chimeric proteins,
CC containing an energy generating protein bound to an energy accepting

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CC protein, in which energy transfer between the generating and accepting
CC proteins can take place. The proteins are useful as a reporter for gene
CC expression within the cell, for example to monitor the effect within the
CC cell of antidiabetic or antiinflammatory drugs. The present sequence
CC represents DNA encoding a chimeric protein of the invention

XX

SQ Sequence 2502 BP; 712 A; 609 C; 647 G; 534 T; 0 U; 0 Other;

Alignment Scores:

Pred. No.:	0	Length:	2502
Score:	4504.00	Matches:	833
Percent Similarity:	100.0%	Conservative:	0
Best Local Similarity:	100.0%	Mismatches:	0
Query Match:	100.0%	Indels:	0
DB:	12	Gaps:	0

US-10-537-971-2 (1-833) x ADL56773 (1-2502)

Qy	1	MetLysIleIleIleLeuSerValIleLeuAlaTyrCysValThrAspAsnCysGlnAsp	20
Db	1	ATGAAGATAATAATTCTGTCTGTATATGGCCTACTGTGTACCGACAACAGTGTCAAGAT	60
Qy	21	AlaCysProValGluAlaGluProProSerSerThrProThrValProThrSerCysGlu	40
Db	61	GCATGTCTCTGTAGAACGGAACCGCCATCAAGTACACCAACAGTCCAACTTCTGTGAA	120
Qy	41	AlaLysGluGlyGluCysIleAspThrArgCysAlaThrCysLysArgAspIleLeuSer	60
Db	121	GCTAAAGAAGGAGAATGTATAGATACCAGATGCGCAACATGTAAACGAGATATACTATCA	180
Qy	61	AspGlyLeuCysGluAsnLysProGlyLysThrCysCysArgMetCysGlnTyrValIle	80
Db	181	GATGGACTGTGTGAAAATAAACCAGGGAAGACATGCTGTAGAATGTGCCAGTATGTGATT	240
Qy	81	GluCysArgValGluAlaAlaGlyTyrPheArgThrPheTyrGlyLysArgPheAsnPhe	100
Db	241	GAATGCAGAGTAGAAGCAGCTGTTATTTAGAACGTTTACGGCAAAAGATTAAATTT	300
Qy	101	GlnGluProGlyLysTyrValLeuAlaArgGlyThrLysGlyGlyAspTrpSerValThr	120
Db	301	CAGGAACCTGGTAAATATGTGCTGGCTAGGGGAACCAAGGGTGGCGATTGGTCTGTAACC	360
Qy	121	LeuThrMetGluAsnLeuAspGlyGlnLysGlyAlaValLeuThrLysThrThrLeuGlu	140
Db	361	CTCACCATGGAGAATCTAGATGGACAGAAGGGAGCTGTGCTGACTAAGACAACACTGGAG	420
Qy	141	ValAlaGlyAspValIleAspIleThrGlnAlaThrAlaAspProIleThrValAsnGly	160
Db	421	GTTGCAGGAGACGTAATAGACATTACTCAAGCTACTGCAGATCCTATCACAGTTAACGGA	480
Qy	161	GlyAlaAspProValIleAlaAsnProPheThrIleGlyGluValThrIleAlaValVal	180
Db	481	GGAGCTGACCCAGTTATCGCTAACCCGTTCACAATTGGTGAGGTGACCATTGCTGTTGTT	540
Qy	181	GluIleProGlyPheAsnIleThrValIleGluPhePheLysLeuIleValIleAspIle	200
Db	541	GAAATACCGGGCTCAATATCACAGTCATCGAATTCTTTAAACTAATCGTGATTGATATT	600
Qy	201	LeuGlyGlyArgSerValArgIleAlaProAspThrAlaAsnLysGlyLeuIleSerGly	220
Db	601	CTGGGAGGAAGATCTGTGAGAATTGCTCCAGACACAGCAAACAAAGGACTGATATCTGGT	660
Qy	221	IleCysGlyAsnLeuGluMetAsnAspAlaAspAspPheThrThrAspAlaAspGlnLeu	240

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|||||
Db      661 ATCTGTGGTAATCTGGAGATGAATGACGCTGATGACTTTACTACAGATGCAGATCAGCTG 720
Qy      241 AlaIleGlnProAsnIleAsnLysGluPheAspGlyCysProPheTyrGlyAsnProSer 260
      |||||
Db      721 GCGATCCAACCCAACATAAACAAAGAGTTCGACGGCTGCCATTCTATGGCAATCCTTCT 780
Qy      261 AspIleGluTyrCysLysGlyLeuMetGluProTyrArgAlaValCysArgAsnAsnIle 280
      |||||
Db      781 GATATCGAATACTGCAAAGTCTGATGGAGCCATACAGAGCTGTATGTCGTAAACAATATC 840
Qy      281 AsnPheTyrTyrTyrThrLeuSerCysAlaPheAlaTyrCysMetGlyGlyGluGluArg 300
      |||||
Db      841 AACCTCTACTATTACACTCTATCCTGTGCCTTCGCTTACTGTATGGGAGGAGAAGAAAGA 900
Qy      301 AlaLysHisValLeuPheAspTyrValGluThrCysAlaAlaProGluThrArgGlyThr 320
      |||||
Db      901 GCTAAACACGTCCTTTTCGACTATGTTGAGACATGCGCTGCGCCGGAACGAGAGGAACG 960
Qy      321 CysValLeuSerGlyHisThrPheTyrAspThrPheAspLysAlaArgTyrGlnPheGln 340
      |||||
Db      961 TGTGTTTTATCAGGACATACTTTCTATGACACATTCGACAAAGCAAGATATCAATTCCAG 1020
Qy      341 GlyProCysLysGluIleLeuMetAlaAlaAspCysTyrTrpAsnThrTrpAspValLys 360
      |||||
Db     1021 GGCCCATGCAAGGAGATTCTGATGGCCGAGACTGTTACTGGAACACATGGGATGTAAAG 1080
Qy      361 ValSerHisArgAspValGluSerTyrThrGluValGluLysValThrIleArgLysGln 380
      |||||
Db     1081 GTTTCACATAGAGACGTCGAATCATACTGAGGTAGAGAAAGTAACAATCAGGAAACAG 1140
Qy      381 SerThrValValAspLeuIleValAspGlyLysGlnValLysValGlyGlyValAspVal 400
      |||||
Db     1141 TCAACTGTAGTAGATCTCATTGTGGATGGCAAGCAGGTCAAGGTTGGAGGAGTGGATGTA 1200
Qy      401 SerIleProTyrSerSerGluAsnThrSerIleTyrTrpGlnAspGlyAspIleLeuThr 420
      |||||
Db     1201 TCTATCCCGTACAGCTCTGAGAACTTCCATATACTGGCAGGATGGAGACATCCTGACG 1260
Qy      421 ThrAlaIleLeuProGluAlaLeuValValLysPheAsnPheLysGlnLeuLeuValVal 440
      |||||
Db     1261 ACGGCCATCCTACCTGAAGCTCTTGTCGTTAAGTTCAACTTTAAGCAGCTCCTTGTAGTT 1320
Qy      441 HisIleArgAspProPheAspGlyLysThrCysGlyIleCysGlyAsnTyrAsnGlnAsp 460
      |||||
Db     1321 CATATCAGAGATCCATTTCGATGGAAAGACATGCGGCATATGTGGTAACATAATCAAGAT 1380
Qy      461 SerThrAspAspPhePheAspAlaGluGlyAlaCysAlaLeuThrProAsnProProGly 480
      |||||
Db     1381 TCAACTGATGATTTCTTTGACGCAGAAGGAGCATGCGCTCTAACCCCAACCCCAAGGA 1440
Qy      481 CysThrGluGluGlnLysProGluAlaGluArgLeuCysAsnAsnLeuPheAspSerSer 500
      |||||
Db     1441 TGTACAGAGGAACAGAAACCAGAAGCTGAGCGACTTTGCAATAATCTCTTTGATTCTTCT 1500
Qy      501 IleAspGluLysCysAsnValCysTyrLysProAspArgIleAlaArgCysMetTyrGlu 520
      |||||
Db     1501 ATCGACGAGAAATGTAATGTCTGCTACAAGCCTGACCGGATTGCCCGATGTATGTACGAG 1560
Qy      521 TyrCysLeuArgGlyGlnGlnGlyPheCysAspHisAlaTrpGluPheLysLysGluCys 540
      |||||
Db     1561 TATTGCCTGAGGGGACAACAAGGATTTTGTGACCATGCTTGGGAGTTCAAGAAAGAATGC 1620
Qy      541 TyrIleLysHisGlyAspThrLeuGluValProProGluCysGlnGlySerThrGluPro 560
      |||||
Db     1621 TACATAAAACATGGAGACACTCTAGAAGTACCACCTGAATGTCAAGGATCCACAGAGCCC 1680
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Qy	561	GlyLeuGluGluValGlyGluIleGluGlnLysGlnLeuGlnLysArgPheGlyGlyPhe	580
Db	1681	 GGCCTGGAGGAGGTGGGGGAGATTGAGCAGAAACAGCTGCAGAAGCGGTTCGGGGGCTTC	1740
Qy	581	ThrGlyAlaArgLysSerAlaArgLysLeuAlaAsnGlnGlySerValSerLysGlyGlu	600
Db	1741	 ACCGGGGCGCCGAAGTCGGCCCCGAAGTTGGCCAACCAGGGATCCGTGAGCAAGGGCGAG	1800
Qy	601	GluLeuPheThrGlyValValProIleLeuValGluLeuAspGlyAspValAsnGlyHis	620
Db	1801	 GAGCTGTTCACCGGGGTGGTGCCATCCTGGTCGAGCTGGACGGCGACGTAACGGCCAC	1860
Qy	621	LysPheSerValSerGlyGluGlyGluGlyAspAlaThrTyrGlyLysLeuThrLeuLys	640
Db	1861	 AAGTTCAGCGTGTCCGGCGAGGGCGAGGGCGATGCCACCTACGGCAAGCTGACCCTGAAG	1920
Qy	641	PheIleCysThrThrGlyLysLeuProValProTrpProThrLeuValThrThrPheGly	660
Db	1921	 TTCATCTGCACCACCGGCAAGCTGCCCCGTGCCCTGGCCCACCCTCGTGACCACCTTCGGC	1980
Qy	661	TyrGlyLeuGlnCysPheAlaArgTyrProAspHisMetLysGlnHisAspPhePheLys	680
Db	1981	 TACGGCCTGCAGTGCTTCGCCCGCTACCCCGACCACATGAAGCAGCAGACTTCTTCAAG	2040
Qy	681	SerAlaMetProGluGlyTyrValGlnGluArgThrIlePhePheLysAspAspGlyAsn	700
Db	2041	 TCCGCCATGCCGAAGGCTACGTCCAGGAGCGCACCATCTTCTTCAAGGACGACGGCAAC	2100
Qy	701	TyrLysThrArgAlaGluValLysPheGluGlyAspThrLeuValAsnArgIleGluLeu	720
Db	2101	 TACAAGACCCGCGCCGAGGTGAAGTTCGAGGGCGACACCCTGGTGAACCGCATCGAGCTG	2160
Qy	721	LysGlyIleAspPheLysGluAspGlyAsnIleLeuGlyHisLysLeuGluTyrAsnTyr	740
Db	2161	 AAGGGCATCGACTTCAAGGAGGACGGCAACATCCTGGGGCACAAGCTGGAGTACAACCTAC	2220
Qy	741	AsnSerHisAsnValTyrIleMetAlaAspLysGlnLysAsnGlyIleLysValAsnPhe	760
Db	2221	 AACAGCCACAACGTCTATATCATGGCCGACAAGCAGAAGAACGGCATCAAGGTGAACCTTC	2280
Qy	761	LysIleArgHisAsnIleGluAspGlySerValGlnLeuAlaAspHisTyrGlnGlnAsn	780
Db	2281	 AAGATCCGCCACAACATCGAGGACGGCAGCGTGCAGCTCGCCGACCACTACCAGCAGAAC	2340
Qy	781	ThrProIleGlyAspGlyProValLeuLeuProAspAsnHisTyrLeuSerTyrGlnSer	800
Db	2341	 ACCCCCATCGGCGACGGCCCCGTGCTGCTGCCCGACAACCACTACCTGAGCTACCACTCC	2400
Qy	801	AlaLeuSerLysAspProAsnGluLysArgAspHisMetValLeuLeuGluPheValThr	820
Db	2401	 GCCCTGAGCAAGACCCCAACGAGAAGCGCGATCACATGGTCCTGCTGGAGTTCTGTGACC	2460
Qy	821	AlaAlaGlyIleThrLeuGlyMetAspGluLeuTyrLys	833
Db	2461	 GCCGCCGGGATCACTCTCGGCATGGACAGCTGTACAAG	2499

Response to Arguments

7. Applicants arguments filed 10 August 2009 have been fully considered. The remarks and amendments to the claims on the one hand are convincing to necessitate the withdrawal of all previous New Matter rejections and objections as outlined above. However, upon further consideration and comparison the issued US Patent 7,544,484 and the instant claims, the Obvious Double Patenting rejection is made (and also made non-provisional).

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SUZANNE M. NOAKES/
Primary Examiner, Art Unit 1656
03 November 2009